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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,429	12/12/2003	Jean-Christophe Francis Audonnet	454313-3159.1	2595

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EXAMINER	
SALVOZA, M FRANCO G	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,429	AUDONNET ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *1-14,16-20,22,23 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,21 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/622,951.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/01/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on February 20, 2007 is acknowledged.

The traversal is on the ground(s) that all of the claims are interrelated, and that the search and examination of the claims will be co-extensive and overlapping; a search would not constitute and undue and serious burden; additionally, there is a disclosed relationship between the species as the members of the first species are all pox viruses suitable for use in the present invention; the members of the second species are all adjuvants for use in the present invention; the species election be rewritten to allow the search and examination of a second poxvirus or a small number of adjuvants; enforcing the present restriction requirement and elections of species would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO.

This is not found persuasive because because as demonstrated in the Restriction, the separate groups and species recite independent and distinct inventions as further indicated by separate status in the art, and separate searches would be required for each, therefore constituting an undue search burden. The Office regrets any additional costs that may incur, however, the restriction is necessary for a proper and thorough examination of the claims. Further, as indicated in the Restriction, in regards to the species, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. In regards to the method, where applicant elects claims directed to the product, and a product claim is

subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-14, 16-20, 22, 23, 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 20, 2007.

Claims 15, 21, 24-28 are under consideration.

Specification

The disclosure is objected to because of the following informalities: the first paragraph of the first page of the specification does not contain accurate priority information. Application 09/622,951 has been issued as U.S. Patent 6713068, and the filing date for 09/622,951 is inaccurate.

Appropriate correction is required.

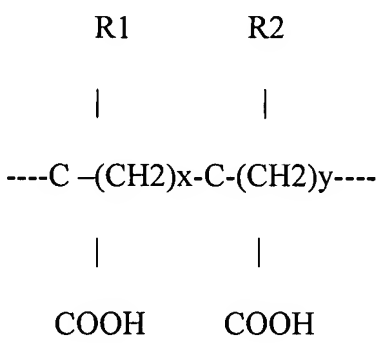
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (U.S. Patent 5990091) in view of Molitor et al. (1985).

Claim 15 recites a vaccine composition against influenza virus in an equine host comprising at least one recombinant virus, selected from canarypox virus containing and expressing in the equine host at least one nucleic acid molecule encoding at least one heterologous influenza protein; and, as an adjuvant, a polymer having monomeric units of the formula:



in which R1 and R2 are identical and are H, x is 0; y is 2; and x+y=2, wherein a single dose of the composition provides immunity against influenza virus; wherein the recombinant virus is a recombinant canarypox virus.

Tartaglia et al. teaches recombinant vectors encoding heterologous or exogenous genes for use in vaccines in any host. Further, Tartaglia et al. teaches the use of canarypox vectors, as well as numerous or "at least one vector" (column 3, lines 10-35); encoding an equine influenza antigen (column 13, line 60); as well as at least one heterologous gene or multiple genes (column 2, line 34) as well as use of an, or any adjuvant (column 23, line 35).

Tartaglia et al. does not teach the polymer having monomeric units of the claimed formula.

Molitor et al. teaches the use of polymers of ethylene maleic anhydride as one adjuvant with immunopotentiating properties, among a list of fourteen different adjuvants, with antiviral and immunoadjuvant activities (p. 216). Regelson et al. (1960) is cited in support to teach the structure of polymers from the EMA series, including hydrolyzed ethylene, which meets the limitations of the elected species.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the recombinant canarypox virus encoding equine influenza antigen of Tartaglia et al. and the EMA adjuvant of Molitor et al. because Tartaglia et al. teaches the use of any adjuvant in combination with the vector vaccines and Molitor et al. teaches EMA as an adjuvant with immunopotentiating properties.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the recombinant canarypox virus encoding equine influenza antigen of Tartaglia et al. and the EMA adjuvant of Molitor et al. because both teach using administration of vaccine compositions using adjuvants to boost immune response.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 15, 21, 24, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (U.S. Patent 5990091) in view of Molitor et al. (1985) and Olsen et al. (1997).

See the recitations to claims 15, 21 above.

Claims 24, 25 recite the vaccine composition of claim 15 wherein the equine influenza protein comprises equine influenza HA protein; wherein the recombinant virus is a canarypox virus.

See the teachings of Tartaglia et al. in view of Molitor et al. above.

Tartaglia et al. in view of Molitor et al. do not teach wherein the equine influenza proteins comprises equine influenza HA protein.

Olsen et al. teaches vaccination using equine influenza HA protein encoded by a gene expressed in a recombinant baculovirus vector (p. 1150).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the gene encoding equine influenza HA protein of Olsen et al. and the vaccine composition of Tartaglia et al. and Molitor et al. because Tartaglia et al. teaches the use of equine influenza HA antigen in recombinant vectors for vaccination.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the gene encoding equine influenza HA protein of Olsen et al. and the vaccine composition of Tartaglia et al. and Molitor et al. because Olsen et al. and Tartaglia et al. both teach immunization with equine influenza HA antigen.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 15, 21, 24, 25, 26, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (U.S. Patent 5990091), Molitor et al. (1985), and Olsen et al. (1997) in further view of Cochran et al. (U.S. Patent 5731188).

See the recitations to claims 15, 21, 24, 25 above.

Claims 26, 27 recite the vaccine composition of claim 15 which comprises two or three recombinant canarypox viruses, each of which contains a nucleic acid molecule that encodes, and each of which expresses, an influenza HA protein from a different influenza strain; which comprises a recombinant canarypox virus that contains nucleic acid molecules that encode, and that expresses, two or three different influenza HA proteins, each of which is from a different strain of influenza virus.

See the teachings of Tartaglia et al., Molitor et al. and Olsen et al. above.

Tartaglia et al., Molitor et al. and Olsen et al. do not teach the vaccine composition of claim 15 which comprises two or three recombinant canarypox viruses, each of which contains a nucleic acid molecule that encodes, and each of which expresses, an influenza HA protein from a different influenza strain; which comprises a recombinant canarypox virus that contains nucleic acid molecules that encode, and that expresses, two or three different influenza HA proteins, each of which is from a different strain of influenza virus.

Cochran et al. teaches recombinant vectors (here, recombinant equine herpesvirus) encoding multiple antigens for equine influenza HA for protection against multiple subtypes (See for example Example 17).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the multiple equine influenza HA genes of Cochran et al. and the recombinant vector embodiments (including multiple vectors) encoding equine influenza antigens, including HA of Tartaglia et al., Molitor et al. and Olsen et al. because Cochran et al. teaches use of multiple equine influenza HA antigens in recombinant vectors for more protective

immunity and broader protection against equine influenza

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the multiple equine influenza HA genes of Cochran et al. and the recombinant vector embodiments encoding equine influenza antigens, including HA of Tartaglia et al., Molitor et al. and Olsen et al. because Cochran et al. and Tartaglia et al. teach recombinant vectors encoding equine influenza antigens for immunity against equine influenza.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 15, 21, 24, 25, 26, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al., Molitor et al., Olsen et al. and Cochran et al. in further view of Oxburgh et al. (1998).

See the recitations to claims 15, 21, 24, 25, 26, 27 above.

Claim 28 recites the vaccine composition of claim 26 or 27, wherein at least one recombinant canarypox virus contains a nucleic acid molecule that encodes and expresses an influenza HA protein from Influenza A/equi-2/Newmarket/2/93.

See the teachings of Tartaglia et al., Molitor et al., Olsen et al. and Cochran et al. above.

Tartaglia et al., Molitor et al., Olsen et al. and Cochran et al. do not teach wherein at least one recombinant canarypox virus contains a nucleic acid molecule that encodes and expresses an influenza HA protein from Influenza A/equi-2/Newmarket/2/93.

Oxburgh et al. teaches the strain Influenza A / equi-2 / Newmarket / 2 / 93 (See Table 1).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the strain of Oxburgh et al. and the recombinant vector embodiments encoding equine influenza antigens, including HA of Tartaglia et al., Molitor et al., Olsen et al. and Cochran et al. because Oxburgh et al. teaches Influenza A / equi-2 / Newmarket / 2 / 93 as a circulating strain of equine influenza virus, and one of ordinary skill in the art would have been motivated to use the strain such as Influenza A / equi-2 / Newmarket / 2 / 93 in order to incorporate additional known, circulating strains to create equine influenza vaccine compositions conferring improved, even broader and more protective immunity.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the strain of Oxburgh et al. and the recombinant vector embodiments encoding equine influenza antigens, including HA of Tartaglia et al., Molitor et al., Olsen et al. and Cochran et al. because Tartaglia et al. and Oxburgh et al. teach equine influenza virus vaccines.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 15, 21, 24, 25, 26, 27, 28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 8, 14, 15, 16, 17 of prior U.S. Patent No. 6713068. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15, 24, 26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 6, 7, 8 of U.S. Patent No. 6558674 in view of Molitor et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite immunogenic compositions comprising plasmids encoding equine influenza virus HA; a carrier; and HA from different strains of EIV.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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